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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,387	03/26/2003	Maurizio Dalle Carbonare	0259-0411PUS1	6340

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EXAMINER

MAEWALL, SNIGDHA

ART UNIT	PAPER NUMBER
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1612

NOTIFICATION DATE	DELIVERY MODE
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09/04/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/019,387	Applicant(s) DALLE CARBONARE ET AL.	
	Examiner Snigdha Maewall	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. Receipt of Applicant's Arguments/Remarks, Amendments and RCE filed on 06/10/08 is acknowledged.

Claims 1-2 remain canceled in this Application.

New claim 19 has been added in this application.

Accordingly, claims **3-19** are pending in this application, claims **3-19** will be prosecuted on the merits.

The rejections made under 35 USC 112.1 made in office action 12/12/07 have been withdrawn in view of applicant's arguments. The rejection made under 35 USC 112.2 made in office action 12/12/07 has been withdrawn in view of Applicant's amendments to the claims.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1612

Claim 3 recites the limitation cross-linked derivative and auto cross-linked ester. It is unclear to the examiner as to what group is cross-linked or autocross-linked. Examiner suggests reciting specific structures.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 3-8, 12 and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Davidson et al. (Clinical materials 8, 171 (1991) of record.

Davidson et al. teaches hyaluronate derivatives and their application to wound healing and wound repair with reduced scarring (see title and page 171, second column). The reference teaches that hyaluronic acid and its derivatives show as biomaterial in wound healing applications. The hyaluronate treated wounds tended to accumulate collagen more slowly hence showing the capacity of such biomaterials in modifying the scarring process. Such ability shows effect in improving wound healing and repair process (see the first page). The reference teaches formulations can be fabricated into gels, films and woven material (see page 172, 1-5 lines. Experimental procedures have been shown on page 172, on both columns. The results show that ability of hyaluronate and its esterified derivatives stimulate early organization of wound

Art Unit: 1612

site while moderating the excessive accumulation of collagen at the stage of scar formation. (see page 174 column2, last paragraph).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson et al. (Clinical materials (1991) in view of Della Valle et al. (USP 5,676,964).

Davidson et al. teaches hyaluronate derivatives and their application to wound healing and wound repair with reduced scarring (see title and page 171, second column). The reference teaches that hyaluronic acid and its derivatives show as biomaterial in wound healing applications. The hyaluronate treated wounds tended to accumulate collagen more slowly hence showing the capacity of such biomaterials in modifying the scarring process. Such ability shows effect in improving wound healing and repair process (see the first page). The reference teaches formulations can be fabricated into gels, films and woven material (see page 172, 1-5 lines. Experimental procedures have been shown on page 172, on both columns. The results show that ability of hyaluronate and its esterified derivatives stimulate early organization of wound

Art Unit: 1612

site while moderating the excessive accumulation of collagen at the stage of scar formation. (see page 174 column2, lat paragraph).

Davidson et al. do not teach various other esters as claimed.

Della et al. teaches inter and intramolecular cross-linked esters of acid polysaccharides in which part or all of the carboxy groups are esterified with hydroxyl groups of the same or different molecules of polysaccharide. The inner cross linked esters of polysaccharide acids are useful in the field of biodegradable plastic materials to surgical articles, in cosmetic and pharmaceutical fields (abstract and all the claims). Acid polysaccharides which undergo esterification is shown to as hyaluronic acid, alginic acid etc. (see column 1, lines 65-67). The activated esters can be of various types such as O-acyl derivatives, pentachlorophenyl esters, esters of N-hydroxysuccinamide esters and trichlorophenyl esters (see column 3, lines 1535).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to use various hyaluronic acid esters for the treatment of scarring on the skin by using the composition provided by Della Valle et al. since Davidson et al. teaches utilization of hyaluronate esters in wound healing and scarring treatment and Della velle et al. teaches that hyaluronic esters can be used in pharmaceutical fields. A skilled artisan would have been motivated to use derivatives of hyaluronic acid such as esters of hyaluronic acid in treating the scarring of the skin and treatment of wound with a reasonable expectation of success.

Response to Arguments

8. Applicant's arguments with respect to claims 17 have been considered but are moot in view of the new ground(s) of rejection.

9. Claims 3-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson et al. (Clinical materials (1991) in view of Della Valle et al. (USP 4,851,521).

The teachings of Davidson et al. have been discussed above. Davidson et al. do not specifically teach various esters which are claimed instantly.

Della Velle et al. teach esters of hyaluronic acid in which all or portion of the carboxylic groups of the acid are esterified. The compounds possess utility in pharmaceutical preparation comprising an active ingredient and hyaluronic ester (abstract). Hyaluronic acid with aliphatic, araliphatic, cycloaliphatic or etherocyclic alcohols are used in the preparation. (see column 2, lines 53-55). Methyl esters of hyaluronic acid and their use in therapeutic uses is described in column 4, lines 65-67). The comparative analysis of hyaluronic acid verses hyaluronic ester has been depicted in column 42 under treatment, results and conclusion, the prevention or treatment of chapped skin is disclosed in column 43, lines 1-7. The reference discloses that the hyaluronic acid esters can be used safely and effectively to augment and correct soft tissue defects as acne scars, atrophy post surgical irregularities, cleft lip scars and age related wrinkles. The formulation can be used as sponges for wounds and various lesions(see column 48, lines 50-65 and claim 27).

Art Unit: 1612

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to use hyaluronic acid ester for the treatment of scarring on the skin by using the composition provided by Della Valle et al. since Davidson et al. teaches utilization of hyaluronate esters in wound healing and scarring treatment and Della Valle et al. teaches application of hyaluronic esters in pharmaceutical fields. A skilled artisan would have been motivated to use derivatives of hyaluronic acid such as esters of hyaluronic acid in treating the scarring of the skin and treatment of wound with a reasonable expectation of success.

Response to Arguments

10. Applicant's arguments with respect to claims 3-19 have been considered but are moot in view of the new ground(s) of rejection.

11. DECLARATION SUBMITTED UNDER 37 C.E.R. § 1.132

Applicant argues that the attached the results of another study conducted, this time using the auto-crosslinked ester of hyaluronic acid presents unexpected result and as can be seen from the results, it is possible to observe that the scarred areas of the group treated with the auto-crosslinked ester of hyaluronic acid are 50% less extensive than the control areas.

The declaration is insufficient to overcome the rejections made in office action dated 12/12/07.

The declaration is not commensurate with the scope of the claims. Declaration only provides example of benzyl hyaluronate esters of hyaluronic acid in treating the

Art Unit: 1612

normotrophic scar, however, the claims are broadly drawn to esters such as hyaluronic acid derivative selected from the group consisting of an ester with an alcohol, an auto-crosslinked ester, a crosslinked derivative, a hemiester of succinic acid with hyaluronic acid, an O-sulphated derivative and an O/N sulphated derivatives. Furthermore, the difference between percent of control and percent of treated area appears to be same in the figure provided in declaration. The declaration, thus does not commensurate with the scope of the claims as recited.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

Application/Control Number: 10/019,387

Page 9

Art Unit: 1612

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore, Ph.D/

Primary Examiner, Art Unit 1612